Surgical Tool for Electrode Implantation

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Field of the Invention

The present invention is generally directed to implantable medical devices, in particular to a tool for implanting electrodes and their association wires.

Background of the Invention

In 1755 LeRoy passed the discharge of a Leyden jar through the orbit of a man who was blind from cataract and the patient saw "flames passing rapidly downwards." Ever since, there has been a fascination with electrically elicited visual perception. The general concepts of electrical stimulation of retinal cells to produce these flashes of light or phosphenes has been known for quite some time. Based on these general principles, some early attempts at devising a prosthesis for aiding the visually impaired have included attaching electrodes to the head or eyelids of patients. While some of these early attempts met with some limited success, these early prosthesis devices were large, bulky and could not produce adequate simulated vision to truly aid the visually impaired.

In the early 1930's, Foerster investigated the effect of electrically stimulating the exposed occipital pole of one cerebral hemisphere. He found that, when a point at the extreme occipital pole was stimulated, the patient perceived a small spot of light directly in front and motionless (a phosphene). Subsequently, Brindley and Lewin (1968) thoroughly studied electrical stimulation of the human occipital cortex. By varying the stimulation parameters, these investigators described in detail the location of the phosphenes produced relative to the specific region of the occipital cortex

stimulated. These experiments demonstrated: (1) the consistent shape and position of phosphenes; (2) that increased stimulation pulse duration made phosphenes brighter; and (3) that there was no detectable interaction between neighboring electrodes which were as close as 2.4 mm apart.

As intraocular surgical techniques have advanced, it has become possible to apply stimulation on small groups and even on individual retinal cells to generate focused phosphenes through devices implanted within the eye itself. This has sparked renewed interest in developing methods and apparati to aid the visually impaired. Specifically, great effort has been expended in the area of intraocular retinal prosthesis devices in an effort to restore vision in cases where blindness is caused by photoreceptor degenerative retinal diseases such as retinitis pigmentosa and age related macular degeneration which affect millions of people worldwide.

Neural tissue can be artificially stimulated and activated by prosthetic devices that pass pulses of electrical current through electrodes on such a device. The passage of current causes changes in electrical potentials across neuronal membranes, which can initiate neuron action potentials, which are the means of information transfer in the nervous system.

Based on this mechanism, it is possible to input information into the nervous system by coding the information as a sequence of electrical pulses which are relayed to the nervous system via the prosthetic device. In this way, it is possible to provide artificial sensations including vision.

One typical application of neural tissue stimulation is in the rehabilitation of the blind. Some forms of blindness involve selective loss of the light sensitive transducers of the retina. Other retinal neurons remain

viable, however, and may be activated in the manner described above by placement of a prosthetic electrode device on the inner (toward the vitreous) retinal surface. This placement must be mechanically stable, minimize the distance between the device electrodes and the neurons, and avoid undue compression of the neurons.

In 1986, Bullara (US Pat. No. 4,573,481) patented an electrode assembly for surgical implantation on a nerve. The matrix was silicone with embedded iridium electrodes. The assembly fit around a nerve to stimulate it.

Dawson and Radtke stimulated cat's retina by direct electrical stimulation of the retinal ganglion cell layer. These experimenters placed nine and then fourteen electrodes upon the inner retinal layer (i.e., primarily the ganglion cell layer) of two cats. Their experiments suggested that electrical stimulation of the retina with 30 to 100 uA current resulted in visual cortical responses. These experiments were carried out with needle-shaped electrodes that penetrated the surface of the retina (see also US Pat. No. 4,628,933 to Michelson).

The Michelson '933 apparatus includes an array of photosensitive devices on its surface that are connected to a plurality of electrodes positioned on the opposite surface of the device to stimulate the retina. These electrodes are disposed to form an array similar to a "bed of nails" having conductors which impinge directly on the retina to stimulate the retinal cells. Such a device increases the possibility of retinal trauma by the use of its "bed of nails" type electrodes that impinge directly on the retinal tissue.

The art of implanting an intraocular prosthetic device to electrically

stimulate the retina was advanced with the introduction of retinal tacks in retinal surgery. De Juan, et al. at Duke University Eye Center inserted retinal tacks into retinas in an effort to reattach retinas that had detached from the underlying choroid, which is the source of blood supply for the outer retina and thus the photoreceptors. See, e.g., E. de Juan, et al., 99 Am. J. Ophthalmol. 272 (1985). These retinal tacks have proved to be biocompatible and remain embedded in the retina, and choroid/sclera, effectively pinning the retina against the choroid and the posterior aspects of the globe. Retinal tacks are one way to attach a retinal array to the retina.

The retina is extraordinarily fragile. In particular, retinal neurons are extremely sensitive to pressure; they will die if even a modest intraocular pressure is maintained for a prolonged period of time. Glaucoma, which is one of the leading causes of blindness in the world, can result from a chronic increase of intraocular pressure of only 10 mm Hg. Furthermore, the retina, if it is perforated or pulled, will tend to separate from the underlying epithelium, which will eventually render it functionless. Thus attachment of a conventional prosthetic retinal electrode device carries with it the risk of damage to the retina, because of the pressure that such a device could exert on the retina.

Byers, et al. received US Pat No. 4,969,468 in 1990 which disclosed a "bed of nails" electrode array which in combination with processing circuitry amplifies and analyzes the signal received from the tissue and/or which generates signals which are sent to the target tissue. The penetrating electrodes are damaging to the delicate retinal tissue of a human eye and therefore are not applicable to enabling sight in the blind.

In 1992 US Pat No. 5,109,844 issued to de Juan et al. on a method of

stimulating the retina to enable sight in the blind wherein a voltage stimulates electrodes that are in close proximity to the retinal ganglion cells. A planar ganglion cell-stimulating electrode is positioned on or above the retinal basement membrane to enable transmission of sight-creating stimuli to the retina. The electrode is a flat array containing 64-electrodes.

Norman, et al. received US Pat No. 5,215,088 in 1993 on a three-dimensional electrode device as a cortical implant for vision prosthesis. The device contains perhaps a hundred small pillars each of which penetrates the visual cortex in order to interface with neurons more effectively. The array is strong and rigid and may be made of glass and a semiconductor material.

US Pat. No. 5,476,494, issued to Edell, et al. in 1995, describes a retinal array held gently against the retina by a cantilever, where the cantilever is anchored some distance from the array. Thus the anchor point is removed from the area served by the array. This cantilever configuration introduces complexity and it is very difficult to control the restoring force of the cantilever due to varying eye sizes.

Sugihara, et al. received US Pat No. 5,810,725 in 1998 on a planar electrode to enable stimulation and recording of nerve cells. The electrode is made of a rigid glass substrate. The lead wires which contact the electrodes are indium tin oxide covered with a conducting metal and coated with platinum containing metal. The electrodes are indium tin oxide or a highly electrically conductive metal. Several lead-wire insulating materials are disclosed including resins.

US Pat. No. 5,935,155, issued to Humayun, et al. in 1999, describes

a visual prosthesis and method of using it. The Humayun patent includes a camera, signal processing electronics and a retinal electrode array. The retinal array is mounted inside the eye using tacks, magnets, or adhesives. Portions of the remaining parts may be mounted outside the eye. The Humayun patent describes attaching the array to the retina using retinal tacks and/or magnets. This patent does not address reduction of damage to the retina and surrounding tissue or problems caused by excessive pressure between the retinal electrode array and the retina.

Mortimer's US Pat NO. 5,987,361 of 1999 disclosed a flexible metal foil structure containing a series of precisely positioned holes that in turn define electrodes for neural stimulation of nerves with cuff electrodes. Silicone rubber may be used as the polymeric base layer. This electrode is for going around nerve bundles and not for planar stimulation.

The retina is also very sensitive to heat. Implanting a retinal prosthesis fully within the eye may cause excessive heat buildup damaging the retina. It is, therefore, advantageous to implant an electrode array on the retina attached by a cable to heat producing electronics which are implanted somewhere outside the eye. If no electronics are implanted in the eye, it is necessary to run one wire for each electrode from the electronics package to the electrode array. These wires must be extremely thin. While grouping them together in a cable with a protective sheath provides some protection, the array and cable must be handled carefully to prevent damage to the electrode array or cable.

Published US patent application 2002/0099420, Chow et al. describes a surgical tool for implantation of a retinal electrode array. The Chow device is a tube which is placed into the eye and to the implant location. Then fluid

flows though the tube pushing the electrode array into place.

Summary of the Invention

The present invention is a surgical tool for implanting an electrode array and its connected cable within an eye. The insertion tool is used to aid the surgeon in pulling the electrode wire and array through the scull, four-rectus muscles of the eye, and the sclera. The insertion tool consists of a medical grade ABS material that is commonly used in various medical products.

The novel features of the invention are set forth with particularity in the appended claims. The invention will be best understood from the following description when read in conjunction with the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a perspective view of the retinal electrode array assembly showing the electrodes and signal conductors as well as mounting aperture for tacking the assembly inside the eye, wherein both the array and its associated electronics are located inside the eye.

FIG. 2 is a perspective view of the retinal electrode array assembly showing the electrodes and signal conductors as well as mounting aperture for tacking the assembly inside the eye, wherein the associated electronics are located outside the eye.

FIG. 3 is a perspective view of the retinal electrode array assembly wherein the array is installed inside the eye and the associated electronics are installed outside the eye at some distance from the sclera wherein the feeder cable contains both a coiled cable leading between the electronics and the sclera and a series of fixation tabs along the feeder cable for securing the feeder cable by suture.

FIG. 4 is a cross-sectional view of the retinal electrode array, the sclera, the retina and the retinal electrode array showing the electrodes in contact with the retina.

FIG. 5 depicts a cross-sectional view of the retinal electrode array showing a strain relief slot, strain relief internal tab and a mounting aperture through a reinforcing ring for a mounting tack to hold the array in position.

FIG. 6 illustrates a cross-sectional view of the retinal electrode array showing a strain relief slot and a ferromagnetic keeper to hold the array in position.

FIG. 7 illustrates a cross-sectional view of the retinal electrode array showing a strain relief slot and a mounting aperture through a reinforcing ring for a mounting tack to hold the array in position, wherein the strain relief internal tab containing the mounting aperture is thinner than the rest of the array.

FIG. 8 is a perspective view of the preferred insertion tool, for inserting the array of figures 1 – 7, having an curved tongs and a spring base.

FIG. 9 is a mechanical drawing of an alternate embodiment of the insertion tool illustrated in figure 8 having straight tongs and a.

FIG. 10 is a perspective view of an alternate embodiment using a hinged base.

FIG. 11 is a perspective view of an alternate embodiment using curved tongs and a hinged base.

Detailed Description of the Preferred Embodiments

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

Fig. 1 provides a perspective view of a preferred embodiment of the retinal electrode array (implanted by the surgical too of the resent invention), generally designated **2**, comprising oval-shaped electrode array body **4**, a plurality of electrodes **6** made of a conductive material, such as platinum or one of its alloys, but that can be made of any conductive biocompatible material such as iridium, iridium oxide or titanium nitride, and single reference electrode **6A** made of the same material as electrode **6**, wherein the electrodes are individually attached to separate conductors **8** made of a conductive material, such as platinum or one of its alloys, but which could be made of any biocompatible conductive material, that is enveloped within an insulating sheath **10**, that is preferably silicone, that carries an electrical

signal to each of the electrodes **6**. "Oval-shaped" electrode array body means that the body may approximate either a square or a rectangle shape, but where the corners are rounded. The reference electrode **6A** is not necessarily stimulated, but is attached to a conductor, as are electrodes **6**. The electrodes could be used in another application as sensors to transmit electrical signals from a nerve. The electrodes **6** transmit an electrical signal to the eye while reference electrode **6A** may be used as a ground, reference, or control voltage.

Electrode array body 4 is made of a soft material that is compatible with the body. In a preferred embodiment array body **4** is made of silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer. In an alternate embodiment the hardness is about 25 or less on the Shore A scale as measured with a durometer. It is a substantial goal to have electrode array body 4 in intimate contact with the retina of the eye.

Strain relief internal tab **12**, defined by a strain relief slot **13** that passes through the array body **4**, contains a mounting aperture **16** for fixation of the electrode array body 4 to the retina of the eye by use of a surgical tack, although alternate means of attachment such as glue or magnets may be used. Reinforcing ring **14** is colored and opaque to facilitate locating mounting aperture **16** during surgery and may be made of tougher material, such as high toughness silicone, than the body of the electrode array body to guard against tearing.

Signal conductors **8** are located in an insulated flexible feeder cable 18 carrying electrical impulses from the electronics **20** to the electrodes **6**, although the electrodes can be sensors that carry a signal back to the

electronics. Signal conductors **8** can be wires, as shown, or in an alternative embodiment, a thin electrically conductive film, such as platinum, deposited by sputtering or an alternative thin film deposition method. In a preferred embodiment, the entire retinal electrode array **2** including the feeder cable 18 and electronics 6 are all implanted inside the eye. Electronics **20** may be fixated inside the eye to the sclera by sutures or staples that pass through fixation tabs **24**. The conductors are covered with silicone insulation.

Grasping handle **46** is located on the surface of electrode array body 4 to enable its placement by a surgeon using forceps or by placing a surgical tool into the hole formed by grasping handle **46**. Grasping handle 46 avoids damage to the electrode body that might be caused by the surgeon grasping the electrode body directly. Grasping handle 46 also minimizes trauma and stress-related damage to the eye during surgical implantation by providing the surgeon a convenient method of manipulating electrode array body **4**. Grasping handle **46** is made of silicone having a hardness of about 50 on the Shore A scale as measured with a durometer. A preferred embodiment of the electrode array body **4** is made of a very soft silicone having hardness of 50 or less on the Shore A scale as measured with a durometer. The reinforcing ring 14 is made of opaque silicone having a hardness of 50 on the Shore A scale as measured with a durometer.

Fig. 2 provides a perspective view of the retinal electrode array assembly **2** wherein the electrode array body **4** is implanted inside the eye and the electronics **20** are placed outside the eye with the feeder cable **18** passing through sclera **30**. In this embodiment, electronics **38** are attached by fixation tabs **24** outside the eye to sclera 30.

Fig. 3 provides a perspective view of retinal electrode array **2** wherein

electrode array body **4** is implanted on the retina inside the eye and electronics 38 are placed outside the eye some distance from sclera 30 wherein feeder cable **18** contains sheathed conductors **10** as silicone-filled coiled cable **22** for stress relief and flexibility between electronics **38** and electrode array body **4**. Feeder cable **18** passes through sclera **30** and contains a series of fixation tabs **24** outside the eye and along feeder cable **18** for fixating cable **18** to sclera **30** or elsewhere on the recipient subject.

Fig. 4 provides a cross-sectional view of electrode array body **4** in intimate contact with retina **32**. The surface of electrode array body **4** in contact with retina **32** is a curved surface **28** substantially conforming to the spherical curvature of retina **32** to minimize stress concentrations therein. Further, the decreasing radius of spherical curvature of electrode array body 4 near its edge forms edge relief **36** that causes the edges of array body **4** to lift off the surface of retina **32** eliminating stress concentrations. The edge of electrode array body **4** has a rounded edge **34** eliminating stress and cutting of retina **32**. The axis of feeder cable **18** is at right angles to the plane of this cross-sectional view. Feeder cable **18** is covered with silicone.

Fig. 5 provides a cross-sectional view of electrode array body **4** showing spherically curved surface **28**, strain relief slot **13** and mounting aperture 16 through which a tack passes to hold array body **4** in intimate contact with the eye. Mounting aperture **16** is located in the center of reinforcing ring **14** that is opaque and colored differently from the remainder of array body **4**, making mounting aperture **16** visible to the surgeon. Reinforcing ring 14 is made of a strong material such as tough silicone, which also resists tearing during and after surgery. Strain relief slot **13** forms strain relief internal tab **12** in which reinforcing ring **14** is located. Stresses that would otherwise arise in the eye from tacking array body **4** to the eye

through mounting aperture **16** are relieved by virtue of the tack being located on strain relief internal tab **12**.

Fig. 6 provides a cross-sectional view of a preferred embodiment of electrode array body **4** showing ferromagnetic keeper **40** that holds electrode array body **4** in position against the retina by virtue of an attractive force between keeper **40** and a magnet located on and attached to the eye.

Fig. 7 is a cross-sectional view of the electrode array body **4** wherein internal tab **12** is thinner than the rest of electrode array body **4**, making this section more flexible and less likely to transmit attachment induced stresses to the retina. This embodiment allows greater pressure between array body **4** and the retina at the point of attachment, and a lesser pressure at other locations on array body **4**, thus reducing stress concentrations and irritation and damage to the retina.

Fig. 8 is a perspective view of the preferred insertion tool **50**. The electrode array body **4** and feeder cable **18** are extremely delicate. They must pass through a hole in the scull, pass under the four-rectus muscles of the eye, through the sclera and be attached to the retina. The insertion tool **50** has a rounded point **52** for gently separating muscle and flesh as the tool is passed through. The rounded point **52** is rigidly attached to a base **54** and top **56**. Both the base **54** and the top **58** are rounded on the outside and square on the inside. The rounding helps the tool pass through flesh without causing damage. The electrode body **4** is place between the base **54** and top **58**. Spring force traps the electrode array body **4** between the base **54** and top **58**. The tool further includes a radius **64** between the base **54** and the top **58**, which provides a space between the base **54** and the top **58** such that even pressure is applied along the length of the base 54 and the top **58**.

The radius **64** reduces stress concentrations that could crack the tool at the junction of the base and top with the base and top are deflected while loading or unloading the electrode array. The even pressure allows a surgeon to hold the electrode array body **4** and feeder cable **18** firmly without causing unnecessary stress on the electrode array body **4**. The tool is fashioned from an inert biocompatible material that includes resilient elastic properties such ABS, stainless steel or titanium. ABS is suitable as a single use, disposable surgical tool while stainless steel or titanium could be steam sterilized and reused.

Once the electrode array body **4** and the feeder cable **18** are safely held in the surgical tool **50**, the surgeon can pass the tool **50**, electrode array body **4** and the feeder cable **18** in the same manner as a needle and thread. The preferred surgical tool **50** is curved to promote easy movement around the eye. The curvature of the tool generally conforms to the curvature of the outside of the sclera. Alternatively the surgical tool may be strait as shown in figure **9**.

Fig. 9 shows an alternate embodiment of the surgical tool **150**. The alternate surgical tool **150** has a strait base **54** and top **58**, while retaining the radius **164** and rounded point **152** of the preferred embodiment. There are advantages to strait and curved surgical tools for much the same reasons there are advantages to strait and curved needles. Different surgeons may prefer different tools.

Fig. 10 shows another alternate embodiment. Rather than relying on spring force to hold the electrode array body **4** and the feeder cable **18** in the tool **250**. The base **254** is rigidly attached to the rounded point **252**, but the top **258** is attached by a hinge **256** to the base **254** and rounded point **252**.

This allows the surgeon more control of the force applied to the electrode array body **4** and the feeder cable **18**. The hinge **256** further provides for easier loading and unloading of the electrode array. This embodiment retains the radius **264** to provide even pressure along the lengths of the base **254** and the top **258**. This embodiment further includes notches **260** in the base **254**, which mate with guides **262** in the top **258** to hold the electrode array body **4** and the feeder cable **18** in the tool **250**, by holding the top **258** and base **254** together. The radius **264** reduces stress concentrations that could crack the tool at the junction of the base and top with the base and top are deflected while loading or unloading the electrode array.

Fig. 11 shows another alternate embodiment, similar to that shown in Figure 12. The base **354** is rigidly attached to the rounded point **352**, but the top **358** is attached by a hinge **356** to the base **354** and rounded point **352**. The hinge **356** further provides for easier loading and unloading of the electrode array. This embodiment retains the radius **264** to provide even pressure along the lengths of the base **354** and the top **358**. However, the base **354** and top **358** are curved to allow for easier insertion of the tool. This embodiment further includes a keeper **360** attached to the base **354**, which covers the top **358** to limit movement and prevents opening the tool and possibly dropping the array body **4**.

While the invention has been described by means of specific embodiments and applications thereof, it is understood that numerous modifications and variations could be made thereto by those skilled in the art without departing from the spirit and scope of the invention.